UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and WILLIAM P. DELANEY

Plaintiffs,

v.

CIVIL ACTION No. 05-CV-10241 (MLW)

ELI LILLY AND COMPANY,

Defendant.

DEFENDANT ELI LILLY AND COMPANY'S OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE AFFIDAVIT OF JOHN J. HEFFERREN

Defendant Eli Lilly and Company ("Lilly") filed a Motion for Summary Judgment in this action arguing that plaintiff Julie Delaney ("plaintiff") cannot identify Lilly as the DES manufacturer that caused her injuries solely on the basis of her mother's description of the DES she took during her pregnancy with plaintiff in 1969 and 1970. Plaintiff recently filed a Motion for Leave to File Affidavit of John J. Hefferren in Opposition to Lilly's Motion for Summary Judgment ("Pls. Motion for Leave"). Plaintiff seeks to use this testimony to bolster her argument that the pill description provided by her mother -- white, cross-scored, uncoated pill with no other markings -- was likely Lilly's DES pill in 1969-'70.

Dr. Hefferren's affidavit should not be allowed into the record because it is untimely under Rule 26(a)(2), prejudicial under Rule 37(c)(1) and on its face incompetent under Rule 56(e). Dr. Hefferren conducted a review of some medications while at the American Medical Association from 1954 to 1959 -- at least ten years before plaintiff was allegedly exposed to DES. His article, *Identification Guide for Solid Dosage Forms*, JAMA, vol. 162, No. 12, December 22, 1962 ("JAMA Guide"), references pills available "in the late 1950s and early 1960s," and significantly, described the DES pills of only 6 of the 109 companies that offered the drug for sale on the national market. Dr. Hefferren's most recent "study" of photographed DES pills is similarly irrelevant because, according to Dr. Hefferren, the pills depicted were "available in the late 1950s and early 1960s." Dr. Hefferren's views about the supposed difficulty of imprinting a cross-score on a pill cannot be based on personal knowledge because Dr. Hefferren has no apparent experience in this area. Dr. Hefferren's speculation on these issues, moreover, have not been tested at deposition.

In addition, Dr. Hefferren's affidavit contains expert testimony subject to the disclosure requirements of Fed. R. Civ. P. 26(a)(2). Plaintiff disclosed Dr. Hefferren's affidavit less than three weeks before the hearing on Lilly's motion for summary judgment. Lilly has been prejudiced because it has not had the opportunity to take Dr. Hefferren's expert deposition, develop Fed. R. Evid. 702 objections to his testimony or disclose a rebuttal expert. Dr. Hefferren's affidavit should be excluded under Rule 37(c)(1) from consideration at summary judgment and at trial.

A. DR. HEFFERREN'S AFFIDAVIT DOES NOT SATISFY THE REQUIREMENTS OF FED. R. CIV. P. 56(e)

Rule 56(e) states that "opposing affidavits shall be made on personal knowledge." Based on the materials attached to Dr. Hefferren's affidavit, it does not appear that he has any personal knowledge about the difficulty of manufacturing a quarter-scored DES pill or the uniqueness of such pills *in 1969 and 1970*, the only years relevant to this litigation. Dr. Hefferren's affidavit should be stricken in accordance with Rule 56(e).

1. Dr. Hefferren's Personal Professional Experience

Dr. Hefferren's affidavit and his *curriculum vitae* indicate that his familiarity with the physical characteristics of solid dosage drugs was limited to his tenure at the American Medical Association from 1954 through 1959. *See* Docket No. 65, App. 1, at 2-3, 6. During that tenure,

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Dr. Hefferren evaluated and classified over 5,000 drugs in solid dosage form. *Id.* at 3. From 1959 through 1977, Dr. Hefferren worked for the American Dental Association as the Director of its Division of Chemistry. *Id.* at 6. There is nothing in Dr. Hefferren's affidavit or his *curriculum vitae* to indicate that he possessed *any* familiarity with the physical characteristics of solid form drugs in 1969-'70, much less the more than 60 varieties of DES products available at that time.

2. Dr. Hefferren's Review of the JAMA Guide

Exhibits C and D to Dr. Hefferren's affidavit indicate that he conducted an extensive review of the 1962 JAMA Guide to determine whether or not any of the drugs described therein were identical to Lilly's 25 mg, quarter-scored DES pill. *Id.* at 13-25. The JAMA Guide described the physical characteristics of over 5,000 different drugs that were available *in the late 1950s and early 1960s. Id.* at 2-3, 18. The Guide could not describe any pills available on the national market in 1969 or 1970. Accordingly, the Guide provided Dr. Hefferren with no knowledge about the physical characteristics of the pills available in 1969-'70. Assuming that Lilly's 25 mg DES pill was the only white, quarter-scored, uncoated DES pill listed in the 1962 Guide *does not* mean that Lilly made the only such pill in 1969-'70.

In fact, Dr. Hefferren cannot even say, based on his review of the JAMA Guide, that Lilly made the only white, quarter-scored, uncoated DES pill *in 1962*. The JAMA Guide failed to describe *the majority* of DES pills that were available on the national market during the 1950s and early 1960s. The Guide classified 23 different DES pills that were made by *only six companies*, one of which was Lilly. According to the 1962 *Drug Topics Red Book* ("Red Book"), there were *109 companies* marketing DES nationally that year. *See* 1962 Drug Topics Red Book, at 194-97 (attached hereto as Ex. 1) (listing 109 manufacturers of "Diethylstilbestrol" in 1962). The JAMA Guide is thus not representative of the various physical characteristics of

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DES pills available on the national market in the 1950s and 1960s, much less the pills available in 1969-'70, which could not have been represented at all.

3. <u>Dr. Hefferren's Review of Irrelevant Pill Photographs</u>

Exhibits C and D to Dr. Hefferren's affidavit indicate that he reviewed 250 photographs of DES pills "available in the late 1950s and early 1960s" that were in the possession of plaintiff's counsel. See Docket 65, App. 1, at 14 (emphasis added). Dr. Hefferren concludes from this review that none of the pills depicted matched the physical description of Lilly's 25 mg DES pill. Id. at 15. That conclusion has nothing to do with whether there were DES pills on the market in 1969 and 1970 that matched the description of plaintiff's mother. Here again, Dr. Hefferren gained no knowledge of the DES pills on the national market in 1969-'70 from reviewing pictures of pills that were available in the late 1950s and early 1960s. He has no basis in personal knowledge to opine that Lilly's DES pill was the only white, quarter-scored, 25 mg DES pill on the market in 1969-'70. Further, Dr. Hefferren does not contend that the array of DES pill photographs he reviewed was exhaustive, or even close to exhaustive, for the "late 1950s and early 1960s." He cannot even say, therefore, that the pill photographs he reviewed indicate that Lilly produced the only white, quarter-scored, 25 mg DES pill in the late 1950s or early 1960s.

4. Portions of Dr. Hefferren's Affidavit That Must Be Stricken Under Rule 56(e) If the Affidavit is Considered by the Court

Should the Court allow Dr. Hefferren's affidavit into the record, Lilly requests that the following statements be stricken in accordance with Rule 56(e) as lacking a basis in personal knowledge insofar as they purport to apply to the years 1969-'70:

• "The quarter-score with the deep bevel on the inside quarter scoring and the perimeter beveling is a very distinct tablet that would be difficult to formulate and manufacture." Docket No. 65, App. 1, at 3.

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- "The small, round, flat shape is unusual amongst diethylstilbestrol tablets (2 in 250)." *Id.* at 15.
- "A woman taking 25 mg diethylstilbestrol tablets of Eli Lilly daily will select this tablet from a group of diethylstilbestrol and other tablets." *Id.*
- "Premise the quarter-scored, Lilly tablet of diethylstilbestrol was not marked with a Lilly symbol or name, but the tablet parameters including the deep quarter scoring make it distinctive." *Id.* at 17.
- "Scored Tablet . . . More difficult to produce." *Id.* at 23.
- "Making scored tablets is not for amateurs and those with limited resources and experienced [sic]." *Id*.

B. EXCLUSION OF DR. HEFFERREN'S AFFIDAVIT UNDER RULE 37(C)(1) IS THE APPROPRIATE SANCTION FOR ITS LATE DISCLOSURE

Plaintiff cites Fed. R. Civ. P. 56(c) for the proposition that an "adverse party prior to the day of the hearing may serve opposing affidavits" as grounds for her disclosure of Dr. Hefferren's affidavit less than three weeks before the hearing on Lilly's summary judgment motion. Pls. Motion for Leave, at 1. Plaintiff's reliance on Rule 56(c) is misplaced here, because the "opposing affidavit" at issue contains expert testimony from a witness whose late disclosure is both unjustified and prejudicial.

1. The Legal Standard for Exclusion Under Rules 26(a) and 37(c)(1)

Rule 26(a)(1) requires parties to disclose the identity of all individuals who have discoverable information that may be used to support claims or defenses. Rule 26(a)(2)(A)-(B) requires parties to disclose the identity of any witnesses who may be used to present expert evidence at trial, along with a report summarizing the substance and basis of their testimony. Rule 26(e)(1) requires parties to supplement at appropriate intervals the automatic disclosures required under Rule 26(a). "These directives are mandatory and self-executing." *Lohnes v. Level 3 Communs, Inc.*, 272 F.3d 49, 59 (1st Cir. 2001)

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To promote compliance with these disclosure and supplementation requirements, Rule 37(c)(1) provides:

A party that without substantial justification fails to disclose information required by this rule or by Rule 26(a) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

According to the First Circuit, Rule 37(c)(1) "clearly contemplates stricter adherence to discovery requirements, and harsher sanctions for breaches of this rule, and the required sanction in the ordinary case is mandatory preclusion." *See Lohnes*, 272 F.3d at 60 (quoting *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998)). Mandatory preclusion can only be avoided if the untimely disclosure was either "substantially justified or harmless." *Id.* at 60-61.

2. There is No Substantial Justification for the Untimely Disclosure of Dr. Hefferren's Affidavit

Dr. Hefferren's testimony was disclosed to Lilly for the first time in this case on April 4, 2007, more than a year after discovery closed on January 31, 2006, and nearly six months after plaintiff filed her Opposition to Lilly's Motion for Summary Judgment on October 5, 2006. *See* Docket Nos. 31, 44. Plaintiff relies on Rule 56(c) to argue that she is allowed to submit opposing affidavits right up until the day before a summary judgment hearing. Pls. Motion for Leave, at 1 (quoting Rule 56(c): "[an] adverse party prior to the day of the hearing may serve opposing affidavits")

The Federal Rules draw a practical distinction between affidavits containing expert testimony subject to Rule 26(a)(2)(A)'s disclosure requirements and affidavits that contain simple observation, supplemental or authentication testimony. *Compare Lohne*, 272 F.3d at 59-60 (excluding report containing expert testimony that was submitted for the first time at summary judgment as a sanction for violating disclosure requirements of Rules 26(a) and

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37(c)(1)) with Christian Methodist Episcopal Church v. Montgomery, 2007 U.S. Dist. LEXIS 5133, *16-17 (D.S.C. Jan. 18, 2007) (allowing individual plaintiffs who were available for deposition during discovery to submit affidavits containing personal observations after summary judgment briefing was complete) and Friends of the Wild Swan, Inc. v. U.S. EPA, 130 F.Supp.2d 1184, 1197 (D. Mt. 1999) (allowing employees of defendants to submit affidavits containing personal observations about the authenticity, timing and content of Clean Water Act submittals just days before a summary judgment hearing was held). The Hefferren affidavit contains expert testimony subject to the disclosure requirements of Rule 26(a).

3. The Late Disclosure of the Hefferren Affidavit Has Prejudiced Lilly

Dr. Hefferren's affidavit and the materials he cites raise a number of critical questions that could only be answered in a deposition. By way of example:

- Dr. Hefferren states that he examined over 250 pictures of DES pills that were available in the late 1950s and early 1960s. Docket No. 65, App. 1, at 14-15, 17. Does Dr. Hefferren have a basis to assert that the pictures he reviewed display all of the DES pills that were on the market during that time? How does Dr. Hefferren opine about pills available in 1969 and 1970 given that the companies that manufactured DES, and the appearance of the DES pills marketed, changed from year to year?
- Dr. Hefferren states that the "quarter score [of Lilly's DES pill] with the deep bevel on the inside quarter scoring and the perimeter beveling is a very distinct tablet that would be difficult to formulate and manufacture [sic]." *Id.* at 3. Understanding that Dr. Hefferren has no experience working for commercial pharmaceutical companies, what qualifies him to opine about the difficulty of manufacturing beveled, quarter-scored pills in the late 1960s and early 1970s?

Lilly cannot properly formulate a Fed. R. Civ. P. 702 objection to Mr. Hefferren's qualifications as an expert without exploring these and other issues. Lilly cannot explore these issues at deposition, or consult and disclose rebuttal exerts, because discovery closed more than a year ago.

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CONCLUSION

For all the foregoing reasons, Lilly respectfully requests that plaintiff's Motion for Leave to File Affidavit of John J. Hefferren be DENIED.

Respectfully submitted,

ELI LILLY AND COMPANY By its attorneys,

/s/ Brian L. Henninger_ James J. Dillon (BBO # 124660) Brian L. Henninger (BBO # 657926) Foley Hoag LLP 155 Seaport Boulevard World Trade Center West Boston, MA 02110-2600 (617) 832-1000

Dated: April 17, 2007

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Timely and Practical Pharmacy Facts

LIST OF MANUFACTURERS

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Explanation of Product and Price Listings on First Page of Product Information Section

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66 cc., cc. (258) Singlesm [B] (BI 19) Tablets, 5 mg., 100c, cc	•••	1	10004, on 6.00° 8.60 25 mg. (1044)	0.6 mg., 100s, as. (1196-C)82 1000s, as. (1196-M) 1.76	100 ms. (240) 100 ms. (240) 100 ms. (240) 1000 ms. (250) Hence Ross & White (25) (HA 51) Tablets 0.5 ms. E.C. 2000 1 mg. E.C. 100s 1 100c 2 ms. 100a 1 100c 25 ms. 100a 1 100c 25 ms. 100a
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1000s, es. 25 mg., 100s, es. 1000s, es.	•••	16.00	Chicago Pharm. [33] (CH 561) Parenteral, Chima, Sc., Vial (54A)	E.C., 190s, es. (1203-C)	1490s 5 mg, 100a
Bios Lahr. (BI \$25) 25 Gm, bot., es	•••	7.00	Street Chimalia	1900a, as. (1198-M) 4.50	25 mg. 160s
Blackman (BL 18)	•••	25.00	Tablets, Chimedie 9.25 mg, S.C. (1608) 160s, etc	1000a aa. (1208-M) 5.56	1000 E.C. 100s
Bine Cross [B] (HA 22) Tablets, 8.5 mg. (T-593)		.28	1000 8,00	\$00s, en. (1185-D) 9.00	Harvey Labs. [B] (HA 72R) Parenteral, Vials
100a, ea	•••	1.16	0.5 mag., S.C. (1500) 1.00 mg., S.C. (1500) 1.00 mg. 1.00	6 mar. 1900, ch. (198-C)	Parenteral, Vials 1 mg/cc. (VIII.) 75
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1 mg. (7-595) 100s, on. 100s, on. 100s, on. 100s, on. 100s, on.	•••	.85	1000s.as. 4.00 S mg., C.T. (1511A)	Tablets, 0.1 mg. (887)	10 mg./ec. 10 ec., ea. (VIS6) 1.50
1999a, ea	•••	1.65	100s, sa. 1.00	Tablets, 9.1 mg. (857) 1000, 98	30 cc., est. (Y757) 1.00
1000s, ed.	:::	2.50	5 mg., 6/C. (1811)	E.C. (540) 100c, ea	6.5 mg., 1606s, gs. (T2559) 1.25 E.C., 1600s, es. (T2567) 1.75
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			Tableta, 4.5 mg. 1.05 E.C., 1006a, ea	100c, ea	10000, 00.
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5 mg., 1900s, on. (147) Brewer Ell (BE 352) Gel-cia, 9.5 mg., 100s, on. 1 mg., 190s, on. 1 mg., 190s, on. 5 mg., 190s, on. 25 mg., 190s, on. 100s, on. 25 mg., 190s, on. 100s, on. 25 mg., 190s, on. Bryant [B] (BE 74) Tablets, 1 mg., 110s, on.		4.95	E (1 1000s 3.26	W.C. (KA9)	5,mg., 500s, en
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